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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/364,967	07/31/1999	KEVIN J. KELLY	P-8035	1149

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EXAMINER	
TSAI, CAROL S W	

ART UNIT	PAPER NUMBER
2857	

DATE MAILED: 12/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/364,967	KELLY ET AL.	
	Examiner	Art Unit	
	Carol S Tsai	2857	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *17 and 20* is/are allowed.

6)☒ Claim(s) *1-16,18,19 and 21-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/21/2003 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 1-16, 19, and 29-35 are rejected under 35 U.S.C. 102(e) as being anticipated by U. S. Patent No. 6,108,579 to Snell et al.

With respect to claims 1, 3, 4, 12, and 29, Snell et al. disclose a method of determining the current status and remaining life of a power source in an implantable neurological tissue stimulator comprising the steps of: assessing the power source voltage of the power source in an implantable neurological tissue stimulator (see col. 7, lines 29-57); determining, based on the assessed power source voltage, where the power source is in its power source life cycle (see col. 4, lines 1-17; col. 5, lines 1-57; col. 9, lines 12-28; and col. 10, lines 23-55); obtaining a used capacity of the power source and a time that the power source has been operating, wherein the used capacity and the time are variables that reflect actual historical power consumption of the implantable neurological tissue stimulator (see Figs. 5 and 7; col. 4, lines 29-44; col. 5, lines 39-57; col. 6, lines 18-25; col. 8, lines 44-62; col. 10, lines 22-49; col. 11, lines 17-32; and col. 12, lines 8-15); and determining the remaining life of the power source based on the used capacity of the power (see col. 5, lines 45-57; col. 8, line 62 to col. 9, line 5; and col. 10, line 41 to col. 11, line 3).

As to claim 2, Snell et al. also disclose the power source voltage being done by connecting the power source to an analog to digital (A/D) converter (see col. 7, lines 34-37).

As to claim 5-8, Snell et al. also disclose determining the probable usage rate of the power source and dividing the determined remaining capacity by the probable usage rate of the power source (see col. 4, lines 37-67; col. 6, lines 38-58; and col. 8, line 6 to col. 9, line 5).

As to claims 9-11, Snell et al. also disclose determining the used capacity of the power source since the last time the implantable neurological tissue stimulator was reprogrammed (see col. 10, lines 22-40 and col. 11, lines 4-16).

As to claim 30, Snell et al. also disclose a device for determining the current status and remaining life of a power source in an implantable neurological tissue stimulator, the device comprising: an implantable neurological tissue stimulator (an implantable cardiac stimulating device 10 shown on Fig. 1), the implantable neurological tissue stimulator having: a source of power (battery 70 shown on Fig. 1); a voltage determining system (monitoring circuit 80 shown on Fig. 1) for determining the voltage of the source of power (see col. 7, lines 46-57); a programmer (programmer 110 shown on Fig. 1) for creating and processing information to be sent to and received from the implantable neurological tissue stimulator, the programmer including a processor (controller 150 shown on Fig. 1) and a memory (memory 170 shown on Fig. 1) attached thereto; a system (telemetry circuit 100 shown on Fig. 1) for communicating information between the implantable neurological tissue stimulator and the programmer; wherein the voltage determining system for determining the voltage of the source of power passes the determined voltage of the source of power to the system for communication (see Fig. 1); and wherein the system for communication passes the determined voltage of the source of power from the implantable neurological tissue stimulator to the programmer and to the processor (see Fig. 1), and wherein the processor determines, based on the determined voltage of the source of power, where the source of power is in its life cycle (see col. 4, lines 1-17; col. 5, lines 1-57; col. 9, lines 12-28; and col. 10, lines 23-55); obtains a used capacity of the power source and a time that the power source has been operating, wherein the used capacity and the

time are variables that reflect actual historical power consumption of the implantable neurological tissue stimulator (see Figs. 5 and 7; col. 4, lines 29-44; col. 5, lines 39-57; col. 6, lines 18-25; col. 8, lines 44-62; col. 10, lines 22-49; col. 11, lines 17-32; and col. 12, lines 8-15); and determines the remaining life of the power source based on the used capacity of the power source and the time that the power source has been operating (see col. 5, lines 45-57; col. 8, line 62 to col. 9, line 5; and col. 10, line 41 to col. 11, line 3).

As to claims 12, 13, 31, and 32, Snell et al. also disclose correlating, in a "look-up table", the power source voltage assessed in the step of assessing the power source voltage to a predetermined "power source capacity remaining"/ "power source capacity used" value.

It is, however, considered inherent that Snell et al. correlating, in a "look-up table", the power source voltage assessed in the step of assessing the power source voltage to a predetermined "power source capacity remaining"/ "power source capacity used" value (see col. 8, lines 44-58), because such correlating is known to be a necessary step in order to make a determination of battery end-of-service in a medical device.

As to claims 14 and 15, Snell et al. also disclose determining the power source capacity used/remaining and then subtracting this value from the total source capacity in where the power source capacity remaining is determined (see col. 8, line 59 to col. 9, line 5).

As to claims 16, 19, 33, and 34, Snell et al. also disclose calculating, using the power source voltage determined in the step of assessing the power source voltage of the power source in an implantable neurological tissue stimulator, the remaining power source capacity by a formula (see col. 9, line 36 to col. 10, line 62).

As to claim 35, Snell et al. also disclose the power source being a battery (battery 70 shown on Fig. 1).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 18 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snell et al. in view of U. S. Patent No. 5,744,931 to Arai et al.

As noted above, with respect to claims 18 and 21, Snell et al. disclose the claimed invention, except calculating the remaining power source capacity/power source capacity used by using a non-linear formula.

Arai et al. teach calculating the remaining power source capacity/power source capacity used by using a non-linear formula (see col. 2, lines 10-16 and col. 3, lines 11-23).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Snell et al.'s method to include calculating the remaining power source capacity/power source capacity used by using a non-linear formula, as taught by Arai et al., in order to approximate the actual relationship between measured power source and remaining power source capacity for estimating an actual battery remaining capacity voltage.

6. Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snell et al. in view of U. S. Patent No. 5,344,431 to Merritt et al.

As noted above, Snell et al. disclose the claimed invention, except for informing the user of where in the power source life the power source is.

Merritt et al. teach informing the user of where in the power source life the power source is (see col. 9, line 66 to col. 10, line 2).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Snell et al.'s method to include informing the user of where in the power source life the power source is, as taught by Merritt et al., in order to alert the patient that that the battery is almost exhausted.

As to claims 23 and 24, Snell et al. also disclose displaying a representation of the percentage of power source capacity used/remaining (see col. 8, lines 6-28).

7. Claims 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snell et al. in view of Merritt et al. as applied to claims 1 and 22 above, and further in view of U. S. Patent No. 5,994,876 to Canny et al.

As noted above, with respect to claims 25-27, Snell et al. in combination with Merritt et al. teach all the features of the claimed invention, but do not disclose determining whether the remaining power source capacity falls within a predetermined limit; alerting the user if the remaining power source capacity falls within a predetermined limit; and alerting the user by trigger an alarm.

Canny et al. teach determining whether the remaining power source capacity falls within a predetermined limit (see col. 8, lines 20-26); alerting the user if the remaining power source capacity falls within a predetermined limit; and alerting the user by trigger an alarm (see col. 8, lines 26-28).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Snell et al. in combination with Merritt et al.'s method to include steps of determining whether the remaining power source capacity falls within a predetermined limit; alerting the user if the remaining power source capacity falls within a predetermined limit; and alerting the user by trigger an alarm, as taught by Canny et al., in order to recharge the battery (Canny et al. col. 8, line 28).

As to claim 28, Snell et al. in combination with Merritt et al. do not disclose triggering an alarm chosen from the group consisting of audible or visual warnings.

Canny et al. teach triggering an alarm chosen from the group consisting of audible or visual warnings (see col. 8, lines 25-28).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Snell et al. in combination with Merritt et al.'s method to include triggering an alarm chosen from the group consisting of audible or visual warnings, as taught by Canny et al., in order to recharge the battery (Canny et al. col. 8, line 28).

8. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Snell et al. in view of U. S. Patent No. 6,099,495 to Kinghorn et al.

As noted above, Snell et al. disclose the claimed invention, except for the power source being a capacitor.

Kinghorn et al. teach the power source being a capacitor (see Abstract, lines 1-4; col. 1, lines 65 to col. 2, line 2; and col. 2, lines 61 to col. 3, line 2).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Snell et al.'s method to include the power source being a capacitor, as taught by Kinghorn et al., in order to power an implantable electrical transducer capable of moving from one position to another for providing treatment for the patient (Kinghorn et al. col. 1, line 67 to col. 2, lines 2).

9. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Snell et al. in view of U. S. Patent No. 5,807,397 to Barreras.

Snell et al. disclose implanting in the patient a pulse generator (pulse generation and delivery circuit 60 shown on Fig. 1) having a power source (battery 70 shown on Fig. 1), and a lead (lead system 30 shown on Fig. 1)) connected to the pulse generator and stimulating nervous tissue with electrical pulses generated by the pulse generator and communicated by the lead and determining the status and remaining life of the power source (see col. 7, lines 29-57).

Snell et al. do not disclose controlling the pulse generator within preset limits by patient to adjust stimulation of nervous tissue.

Barreras teaches controlling the pulse generator within preset limits by patient to adjust stimulation of nervous tissue (see col. 18, lines 31-46 and col. 19, lines 18-23).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Snell et al.'s method to include controlling the pulse generator within preset limits by patient to adjust stimulation of nervous tissue, as taught by Barreras, in order that stimulation parameters or control values in the implanted stimulator can be adjusted within preset limits to function effectively.

10. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Snell et al. in view of Merritt et al. as applied to claims 1, 22, and 23 above, and further in view of U. S. Patent No. 5,807,397 to Barreras.

Snell et al. disclose implanting in the patient a pulse generator (pulse generation and delivery circuit 60 shown on Fig. 1) having a power source (battery 70 shown on Fig. 1), and a lead (lead system 30 shown on Fig. 1)) connected to the pulse generator and stimulating nervous tissue with electrical pulses generated by the pulse generator and communicated by the lead and determining the status and remaining life of the power source (see col. 7, lines 29-57).

Snell et al. in combination with Merritt et al. do not disclose controlling the pulse generator within preset limits by patient to adjust stimulation of nervous tissue.

Barreras teaches controlling the pulse generator within preset limits by patient to adjust stimulation of nervous tissue (see col. 18, lines 31-46 and col. 19, lines 18-23).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Snell et al. in combination with Merritt et al.'s method to include controlling the pulse generator within preset limits by patient to adjust stimulation of nervous

tissue, as taught by Barreras, in order that stimulation parameters or control values in the implanted stimulator can be adjusted within preset limits to function effectively.

11. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Snell et al. in view of Merritt et al. and Canny et al. as applied to claims 1, 22, 25, 26, and 27 above, and further in view of U. S. Patent No. 5,807,397 to Barreras.

As to claim 39, Snell et al. disclose implanting in the patient a pulse generator (pulse generation and delivery circuit 60 shown on Fig. 1) having a power source (battery 70 shown on Fig. 1), and a lead (lead system 30 shown on Fig. 1) connected to the pulse generator and stimulating nervous tissue with electrical pulses generated by the pulse generator and communicated by the lead and determining the status and remaining life of the power source (see col. 7, lines 29-57)

Snell et al. in combination with Merritt et al. and Canny et al. do not disclose controlling the pulse generator within preset limits by patient to adjust stimulation of nervous tissue.

Barreras teaches controlling the pulse generator within preset limits by patient to adjust stimulation of nervous tissue (see col. 18, lines 31-46 and col. 19, lines 18-23).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Snell et al. in combination of Merritt et al. and Canny et al.'s method to include controlling the pulse generator within preset limits by patient to adjust stimulation of nervous tissue, as taught by Barreras, in order that stimulation parameters or control values in the implanted stimulator can be adjusted within preset limits to function effectively.

Allowable Subject Matter

12. Claims 17 and 20 are allowed.

13. The following is a statement of reasons for the indication of allowable subject matter:

U. S. Patent No. 5,344,431 to Merritt et al. is the reference closest to the claimed invention. Merritt et al. disclose a method of determining the current status and remaining life of a power source in an implantable neurological tissue stimulator comprising the steps of: assessing the power source voltage of the power source in an implantable neurological tissue stimulator; determining, based on the assessed power source voltage, where the power source is in its power source life cycle; and taking appropriate action in response to the determination of where the power source is in its power source life cycle. However, Merritt et al. do not teach calculating the remaining power source capacity by using a formula of the form: Remaining Battery Capacity = a constant + a constant multiplied by the power source voltage determined in the step of assessing the power source voltage of the power source in an implantable neurological tissue stimulator; and including all of the other limitations in the respective independent claims.

Response to Arguments

14. Applicant's arguments filed 10/21/2003 have been fully considered but they are not persuasive.

Applicants argue that the claims contemplating determining end of life of measurement of actual usage information, while the prior art being limited to measuring preprogrammed usage

information to determine end of life. The Examiner disagrees with Applicants. "Programmer 10 receives the battery voltage information from IPG 4 through programmer telemetry system 16. Programmer telemetry system 16 passes the battery voltage information to a processor 28. Processor 28 includes a memory 30 that includes a "look-up" table embedded with correlated information about the battery voltage and the corresponding battery capacity information. Memory 30 may be either volatile such as RAM or read-only such as EEPROM or other types as will occur to those skilled in the art. This battery capacity information may be either the battery capacity used or the battery capacity remaining. An example of such a "look-up" table is shown in Figure 5 for a Lithium Combination Silver Vanadium Oxide (CSVO) battery. In this example, the battery capacity information is battery capacity used. In either case, either the battery capacity used or battery capacity remaining is determined experimentally by correlating measured battery voltages with either the measured battery capacity used or the measured battery capacity remaining. Thereafter, the battery voltages and the corresponding battery capacity information, whether battery capacity used or battery capacity remaining, are loaded into memory 30 through the "look-up" table" described at pages 11-12 of Applicants' Specification clearly indicates that battery capacity information stored in look-up table shown in Fig. 5 being generated by programmer and passed to the processor by programmer telemetry system is also related to preprogrammed usage information to determine end of life.

Contact Information

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carol S. Tsai whose telephone number is (703) 305-0851. The

examiner can normally be reached on Monday-Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marc S. Hoff can be reached on (703) 308-1677. The fax number for TC 2800 is (703) 308-7382. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the TC 2800 receptionist whose telephone number is (703) 308-1782.

In order to reduce pendency and avoid potential delays, Group 2800 is encouraging FAXing of responses to Office actions directly into the Group at (703) 308-7382. This practice may be used for filing papers not requiring a fee. It may also be used for filing papers which require a fee by applicants who authorize charges to a PTO deposit account. Please identify the examiner and art unit at the top of your cover sheet. Papers submitted via FAX into Group 2800 will be promptly forwarded to the examiner.

Carol S. W. Tsai
Patent Examiner
Art Unit 2857

12/09/03